



INVESTOR IN PEOPLE

**PRIORITY  
DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

The Patent Office

Concept House

Cardiff Road

Newport

South Wales

NP10 8QQ

REC'D 0 4 MAY 2004

WFO

PCT

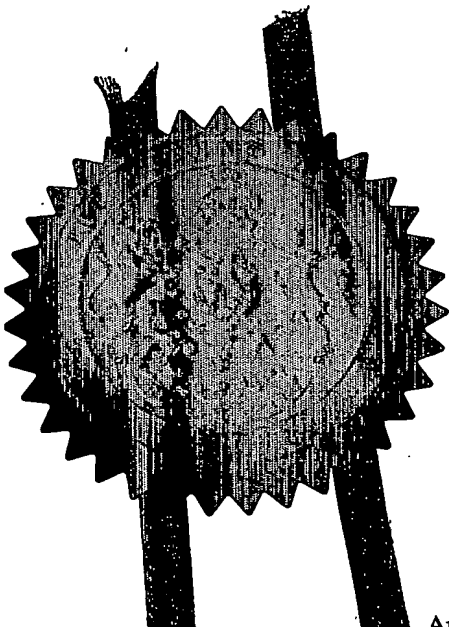
I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

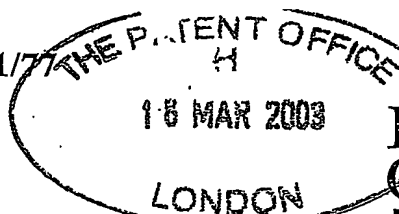
Best Available Copy



Signed

*R. Mahoney*

Dated 21 April 2004



The  
Patent  
Office

1/77

The Patent Office  
Cardiff Road  
Newport  
Gwent NP9 1RH

# Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

18 MAR 2003

1. Your reference	38.80062		
2. Patent application number (The Patent Office will fill in this part)	0306176.9		
3. Full name, address and postcode of the or of each applicant (underline all surnames)	Imperial College Innovations Limited 47 Prince's Gate Exhibition Road London. SW7 2QA		
Patents ADP number (if you know it)	7409436001		
If the applicant is a corporate body, give country/state of incorporation	England		
4. Title of the invention	Tubing		
5. Name of your agent (if you have one)	Frank B. Dehn & Co.		
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	179 Queen Victoria Street London EC4V 4EL		
Patents ADP number (if you know it)	166001		
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)	
8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if: a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body. See note (d))	Yes		

## Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description

16 —

Claim(s)

2 —

Abstract

1 —

Drawing(s)

5 + S Jm L

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

1 ✓

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date 18 March 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

A.J. Piésold  
020 7206 0600

### Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

### Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s) of the form. Any continuation sheet should be attached to this form.
- If you have answered 'Yes', Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

80062.620

Tubing

5 This invention relates to artificial or modified natural body fluid flow tubing and to tubing in other biomedical applications.

It is known from WO 95/09585 to provide a vascular prosthesis comprising a length of generally hollow tubing having openings at both ends thereof and  
10 including a non-planar curved portion so as to induce swirl flow in blood flowing through the curved portion. As explained in that publication, the swirl flow induced by skewing of the blood flow within the non-planar curved portion improves flow characteristics and reduces  
15 the potential for deposit build-up and vascular disease including intimal hyperplasia.

In WO 98/53764, there is disclosed a stent for supporting part of a blood vessel. The stent includes a supporting portion around which or within which part of  
20 a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part. The supporting portion of the stent is shaped so that flow between graft and host vessel is caused to follow a non-planar curve. This generates a swirl flow,  
25 again to provide a favourable blood flow velocity pattern which reduces the occurrence of vascular disease, particularly intimal hyperplasia.

In WO 00/32241, there is disclosed another type of stent, in this case including a supporting portion  
30 around which or within which part of an intact blood vessel other than a graft can be placed. This supporting portion can prevent failure of the vessel through blockage, kinking or collapse. Again, the supporting portion of the stent is of a shape and/or  
35 orientation whereby flow within the vessel is caused to follow a non-planar curve. Favourable blood flow velocity patterns can be achieved through generation

therein of swirl flow within and beyond the stent. Failures in blood vessels through diseases such as thrombosis, atherosclerosis, intimal hyperplasia can be significantly reduced.

5 Further aspects of how swirl flow is beneficial are explained in the above publications. It is further explained in Caro et al. (1998) J. Physiol. 513P,2P how non-planar geometry of tubing inhibits flow instability.

10 In certain embodiments of the above publications the artificial or modified natural blood flow tubing is helical or part-helical. In the case of part-helical tubing, the prosthesis or the supported vessel may undergo less than one complete turn of a helix, for example less than one half or less than one quarter of  
15 such a turn. In this specification, the "swept width" of a helix means the outer width of the helix when viewed axially of the helix. In cases where this swept width is relatively wide compared to the width of the tubing itself, the prosthesis or stent may be more bulky  
20 than is necessary or acceptable to induce the required swirl flow.

It has been proposed in WO 00/38591 to use internal helical grooving or ridging to induce helical flow. However, the use of ribs or grooves in an otherwise  
25 cylindrical tube may not reliably induce swirl flow across the entire cross-section of flow. There may be a tendency for the flow nearer to the centre of the tube to follow a linear path, particularly for flows at  
higher Reynolds numbers. Furthermore, the ratio of the  
30 wetted perimeter to the cross-sectional area of a tube is increased by the provision of ridges or grooves. This may lead to increased flow resistance and a consequent pressure loss, and damage to blood vessels and blood cells and the development of pathology.

35 It is also proposed in WO 00/38591 to use a non-circular cross-section tube which is twisted. Again, however, a departure from circularity increases the

ratio of the wetted perimeter to the cross-sectional area and will have disadvantages.

5 A further proposal in WO 00/38591 is to provide a circular-section tube bent into a cork screw shape. It is usual for the helix of a cork screw to have a clear gap down the middle, so that this proposed configuration would have a wide swept width compared to the width of the tubing, certainly more than two tubing diameters. The amplitude of the helix would be greater than one  
10 half of the internal diameter of the tubing. This proposal would therefore be relatively bulky and unsuitable for certain applications.

Various designs of elastomeric arterial graft prostheses are proposed in GB 2092894. In the version  
15 of Figure 8 of that document, the interior surface is undulatory or corrugated, with different undulations either having parallel circumferential paths or joined in a "spiral" path. The corrugations are proposed as an alternative to reinforcement for improving the anti-  
20 kinking characteristics of the graft. In the case of the "spiral" corrugations which appear to be shown in Figure 8, the angle of the corrugations to the longitudinal axis is relatively high, of the order of more than 70°. This is to be expected where the purpose  
25 of the corrugations is to improve anti-kinking or other structural characteristics, rather than for reasons relating to the nature of the blood flow through the graft. In fact, it is likely that the corrugations would tend to cause the flow to undergo sharp changes of  
30 direction leading to flow separation and the creation of stagnant near-wall regions.

According to the invention, there is provided artificial or modified natural body fluid flow tubing, or flow tubing used in equipment for conveying body  
35 fluid, comprising a portion wherein the centre line of the tubing portion follows a substantially helical path with a helix angle less than or equal to 65°, and

wherein the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion.

5 Certain preferred embodiments are concerned with artificial or modified natural flow tubing of the human or animal body, more particularly artificial or modified natural blood flow tubing. The invention is particularly suitable for in vivo tubing, such as vascular prostheses and stents (external or internal to  
10 intact blood vessels or blood vessels intended for grafting). It is very suitable for vascular access grafts because (unlike with tubing having a large amplitude helix relative to its internal diameter) the tubing can be readily punctured with a needle to allow  
15 blood to be withdrawn for e.g. dialysis.

The tubing portion according to the invention improves flow characteristics. As is well known, in the case of straight tubes, near wall velocities are very low compared to velocities at the core of the tube, due  
20 to the effects of viscosity. In the case of tubes which are bent in a single plane, the speed of the flow at the outside of the bend is increased but the speed of the flow at the inside is retarded further. In both cases, there is considerable variation in axial velocity across  
25 the width of the tube. With the use of a helical tubing portion according to the invention, a swirl flow is generated and the axial velocity profile of the flow across the tubing portion becomes generally more uniform or "blunter", with the axial velocity of flow at both  
30 the outside and inside of the tubing portion being closer to the mean axial velocity.

Thus, the flow characteristics are improved by causing swirling and a relatively uniform distribution of axial and near wall velocity. Mixing over the cross  
35 section is also promoted and there is a reduction in the likelihood of occurrence of flow instability. The avoidance and flushing of stagnant zones is assisted.

There is a reduction in the potential for deposit build up within and downstream of the tubing portion and the development of pathology.

5 In this specification, the amplitude of the helix refers to the extent of displacement from a mean position to a lateral extreme. So, in the case of the tubing having a helical centre line, the amplitude is one half of the full lateral width of the helical centre line.

10 In the tubing of the invention in which the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing, there is a "line of sight" along the lumen of the tubing, unlike in the case of a corkscrew configuration where in effect the  
15 helix is wound around a core (either solid, or "virtual" with a core of air). We have found that the flow at the line of sight generally has a swirl component, particularly for higher Reynolds numbers, even though it could potentially follow a straight path.

20 For the purposes of this specification, the term "relative amplitude" of a helical tubing is regarded as the amplitude divided by the internal diameter. So, in the tubing of the invention in which the amplitude of the helical tubing is less than or equal to one half of  
25 the internal diameter of the tubing, this means that the relative amplitude is less than or equal to 0.5. Relative amplitudes less than or equal to 0.45, 0.40, 0.35, 0.30, 0.25, 0.20, 0.15, 0.1 or 0.05 may be preferred.

30 The relative amplitude may vary according to the use of the tubing and the spatial constraints on its design. It will however be appreciated that by keeping the amplitude less than half the tubing internal diameter a swirling flow may be induced without creating  
35 an excessively large device. Indeed, with small relative amplitudes the shape of the tubing approaches that of a cylinder, as traditionally used in arterial



stents, for example.

The angle of the helix is also a relevant factor in balancing the space constraints on blood flow tubing with the desirability of maximising the cross-sectional area available for flow. The helix angle is preferably less than or equal to  $65^\circ$ , more preferably less than or equal to  $55^\circ$ ,  $45^\circ$ ,  $35^\circ$ ,  $25^\circ$ ,  $20^\circ$ ,  $15^\circ$ ,  $10^\circ$  or  $5^\circ$ . As with relative amplitudes, the helix angle may be optimized according to the conditions: viscosity, density and velocity of fluid.

Generally speaking, for higher Reynolds numbers the helix angle may be smaller whilst satisfactory swirl flow is achieved, whilst with lower Reynolds numbers a higher helix angle will be required to produce satisfactory swirl. The use of higher helix angles will generally be undesirable, as there may be near wall pockets of stagnant fluid. Therefore, for a given Reynolds number (or range of Reynolds numbers), the helix angle will preferably be chosen to be as low as possible to produce satisfactory swirl. Lower helix angles result in smaller increases in length as compared to that of the equivalent cylindrical tubing. In certain embodiments, the helix angle is less than  $20^\circ$ .

It will be appreciated that in pulsatile flow, the Reynolds number will vary over a range. Typical time average mean resting arterial blood flow Reynolds numbers are about 100, reaching peak values of two or three times that in pulsatile flow and three to four times the mean during exertion. Therefore the extent to which swirl flow is promoted will vary likewise. Even if there are stagnant flow regions at lower Reynolds numbers, because for example a low helix angle and/or a low relative amplitude has been selected, these will tend to be flushed out during periods of flow when the Reynolds numbers are higher.

The tubing portion may be made with substantially the same relative amplitude and helix angle along its

length. There may be small variations when the tubing is in use, caused by elongation or contraction of the tubing portion due to tensile loading or caused by torsional loading. However, there may be circumstances in which the tubing portion has a variable helix angle and/or relative amplitude, either to suit the space constraints or to optimise the flow conditions. When the amplitude varies, the tubing will be in the nature of a spiral.

For reasons of manufacturing simplicity, it may be preferred for the tubing portion to have a substantially constant cross-sectional area along its length. Again, there may be variations in use caused by loading on the tubing portion.

The helical tubing portion may form just part of the overall length of tubing or it may extend over substantially its entire length. For example, a stent or prosthesis may have a tubing portion with the geometry of the invention over part of its length or over substantially its entire length.

The helical tubing portion may undergo a fraction of one complete turn, for example one quarter, one half or three quarters of a turn. For example, it may be beneficial in the case of stents, such as internal arterial stents, for the helical tubing portion to undergo less than one complete turn. This would facilitate adoption by the vessel of the required helical shape, rather than the shape "swept out" by the tubing portion.

Alternatively, the helical tubing portion undergoes at least one turn, more preferably at least a plurality of turns. Repeated turns of the helix along the tubing portion will tend to ensure that the swirl flow is maintained.

The tubing, including the tubing portion, may extend generally linearly. In other words, the axis about which the centre line of the tubing portion

follows a substantially helical path, may be straight. Alternatively the axis may itself be curved, whereby the envelope occupied by the tubing is curved, for example to produce an "arch" shaped tubing. The bend of the arch may be planar or non-planar, but should be such that swirl is maintained and certainly not cancelled by the geometry of the bend. Thus, for example, a prosthesis or stent may be generally "arch" shaped (planar or non-planar), having the geometry in accordance with the invention, i.e. being in the form of a tubing portion following a substantially helical path with a helix angle less than or equal to  $65^\circ$ , and with an amplitude less than or equal to one half of the internal diameter of the tubing portion.

In general, the helical centre line of the tubing portion is defined by the tubing portion itself and is not due to a branch in the tubing. The tubing portion may interface with another portion or a branch which may be planar or non-planar. The interface between the helix of the tubing portion and the branch will be such that swirl is maintained, and not cancelled by, the geometry of the branch.

Preferably, the tubing comprises a pharmaceutical coating. Such a coating could be provided to provide sustained release of the pharmaceutical over a period of time. So, the blood flow tubing could provide a pharmaceutical for initial treatment of a disease, and in the longer term the tubing portion gives a therapeutic benefit due to the characteristics which it imparts to the flow.

In the above prior art proposals using grooves or ridges or non-circular sections, where the tubing is substantially straight, then the centre line of the tubing is also straight, unlike the centre line of the tubing portion of the present invention which follows a substantially helical path. Thus, the tubing portion of the invention may have a circular cross-section and thus

the smallest possible wetted perimeter to cross-sectional area ratio, whilst still having the necessary characteristics to induce swirl flow. Of course, there may be circumstances in which the tubing portion of the present invention has a non-circular cross-section, for example to assist interfacing or where pressure loss considerations are not significant.

Further concerning the prior art proposals using grooves or ridges, it should be noted that arterial geometry is under normal physiological conditions non-planar (i.e. its centre line curved in more than one plane in the nature of a helix) and arteries are not grooved or rifled. We have found experimentally that at higher relevant Reynolds numbers, the flow in a helical (non-planar) geometry differs from that in a rifled/grooved geometry, e.g. there is swirling of both near-wall flow and core flow in the former case. The development of swirl flow is more rapid than in the case of rifled/grooved tubing, where swirl flow can take many tubing diameters to develop. Thus, there is the expectation that the introduction of the physiological non-planar geometry (unlike grooved or rifled geometry) will be beneficial in respect of inhibiting the development of pathology.

Because the tubing portion of the invention has a helical centre line, there is spatial reorganisation of vortical structures, which results in motion of the core or cores of the axial flow across the section of the tubing portion, promoting mixing across the cross section. The swirl inhibits the development of stagnation and flow separation regions and stabilises flows.

In the case of the prior art proposals using grooves, ridges or twisted tubes of a non-circular cross-section, the centre line is straight, not helical. Whilst this can be expected to stabilise flow at sharp bends, it does not in straight tubes cause spatial

reorganisation of vortical structures, resulting in motion of the core or cores of the axial flow across the section of the tube. Thus it does not promote mixing across the cross section to the same extent as tubing according to the invention. Such mixing may be important in maintaining the mass transport and physiological integrity of the blood vessels.

The tubing geometry disclosed herein may be used as an internal stent in various biomedical applications e.g. in various arteries (such as in the coronary and renal arteries), in veins, and in non-cardiovascular applications such as in the gastro-intestinal system (e.g. bile or pancreatic ducts), genito-urinary system (e.g. ureter or urethra) or the respiratory system (lung airways). Thus, the invention extends to flow tubing for body fluids other than blood.

Moreover, the tubing may be used in equipment for conveying body fluid. Examples are cardiopulmonary bypass equipment, kidney haemodialysis equipment and blood administration or withdrawal equipment. The tubing geometry may be used in surgical cannulae, as a further improvement of the cannulae disclosed in WO 96/18428. In general, the use of the tubing geometry of the invention can avoid the presence of stagnant regions, and hence be beneficial.

Certain preferred embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, in which:

---

Figure 1 is an elevation view of a tubing portion in accordance with the invention;

Figure 2 is a perspective view of a vascular graft;

Figure 3 is a perspective view of another vascular graft;

Figure 4 is a perspective view of a stent;

Figure 5 is a perspective view of another stent;

Figure 6 is a perspective view of the stent of Figure 5 internally supporting an arterial graft part;

Figure 7 is a perspective view of an internal arterial stent;

Figure 8 shows elevation views of tubing portions used in experiments; and

5        Figure 9 shows elevation views of tubing portions used in further experiments.

The tubing portion 1 shown in Figure 1 has a circular cross-section, an external diameter  $D_e$ , an internal diameter  $D_i$  and a wall thickness  $T$ . The tubing  
10        is coiled into a helix of constant amplitude  $A$  (as measured from mean to extreme), constant pitch  $P$ , constant helix angle  $\theta$  and a swept width  $W$ . The tubing portion 1 is contained in an imaginary envelope 20 which extends longitudinally and has a width equal to the  
15        swept width  $W$  of the helix. The envelope 20 may be regarded as having a central longitudinal axis 30, which may also be referred to as an axis of helical rotation. The illustrated tubing portion 1 has a straight axis 30, but it will be appreciated that in alternative designs  
20        the central axis may be curved. The tubing portion has a centre line 40 which follows a helical path about the central longitudinal axis 30.

It will be seen that the amplitude  $A$  is less than the tubing internal diameter  $D_i$ . By keeping the  
25        amplitude below this size, the space occupied by the tubing portion can be kept relatively small, whilst at the same time the helical configuration of the tubing portion promotes swirl flow of fluid along the tubing portion.

30        Figure 2 shows a prosthesis 10 comprising a length of hollow tubing having an inlet 2 at one end and an outlet 3 at the other end. A generally helical tubing portion 1 is provided at the outlet 3 thereof. The prosthesis has inlet 2a and outlet 3a flaps at its ends  
35        which have been surgically fastened by suturing to regions of an artery remote from a blockage 7 in the artery, the prosthesis thus acting as an arterial bypass

graft. It could also be surgically connected between an artery and a vein so as to serve as a vascular access graft for e.g. renal dialysis.

5 Blood from the circulatory system can flow from the inlet 2 to the outlet 3 along a hollow interior or lumen 4. The helically formed tubing portion 1 is disposed adjacent to the outlet 3. Its non-planar curvature induces a swirl to the flow to improve circulation and resist the formation of potentially damaging deposit  
10 build up and pathology within the interior. The swirl flow may also resist the build up of intimal hyperplasia at the join and downstream of the join with the vein or artery. The tubing can be made of suitable bio-compatible material and such materials are commercially  
15 available and known to those skilled in the art. In order to maintain the tubing open and prevent collapse or kinking it is possible to use a stent or other structural support of plastic, metal or other material internally, externally or integral to the wall of the  
20 tubing.

It will be seen that the prosthesis 10 in Figure 3 is generally arch shaped. This arch may itself be provided in a single plane. If the arch is non-planar then this will also tend to induce swirl flow and it  
25 will be important to ensure that the swirl flow induced by the non-planar arch is in the same direction as that induced by the helical tubing portion 1.

The arrangement of Figure 3 is similar to that of Figure 2, except that the helically formed tubing  
30 portion 1 extends substantially the full length of the prosthesis 10. This type of arrangement may simplify manufacture as the tubing could be made in a continuous length which simply has to be cut to appropriate shorter lengths to form prostheses.

35 Part of the envelope 20 within which the tubing portion 1 is defined is shown in Figure 3. The swept width W defines the width of the envelope. The

longitudinal axis 30 of the envelope is curved, the tubular portion being arch shaped. The centre line 40 follows a helical path about the axis 30.

5 Figure 4 shows an internal stent 12 for use in a graft vessel or an intact vessel. The stent 12 is fabricated from a linked wire mesh and has a helical form along substantially the whole length the stent. The material used is preferably a shape memory alloy to facilitate insertion of the stent.

10 Figure 5 shows an alternative embodiment of an internal stent 12, in which the linked wire mesh has a helical tubing portion 1 only over a short region at one end thereof.

15 Figure 6 shows the stent 12 located in a graft 14 post insertion. The graft 14 surgically attached to an artery 6 has been shown transparent for purposes of illustration, to show the internally located, part helical wire mesh stent in-situ.

20 In the case of the internal stents of Figures 5, 6 and 7, in order to avoid the mesh itself forming a honeycomb of stagnant regions, a modification may involve providing the mesh with a smooth internal lining. Alternatively, an inner layer of the stent may be helically wound, without linkages, as described in WO  
25 01/45593.

As with the prostheses embodiments, the helical form of the stents is arranged to promote swirl flow and thereby minimise the chance of build up of deposits, flow instability and development of pathology.

30 External stents of helical form may also be provided. This type of stent is implanted over a venous arterial or prosthetic graft or intact blood vessel to cause the geometrical configuration of the graft or vessel, e.g. artery, to adopt a predetermined form to  
35 promote swirl flow. External stents may for example be made of a thermosettable plastic, biodegradable material, or a supported synthetic woven material, in



the form of a hollow tube, the walls of which contain numerous openings, or have a micro- or macro-porosity, so that the exterior of the graft or vein is not fully shielded.

5       The stents shown in Figures 4 and 5 are defined within an envelope with a curved longitudinal axis. They are generally arch shaped. Such an arch may curve in a single plane or may itself be non-planar, in which case the non-planarity should promote swirl flow in the  
10       same direction as the helix.

      The stents need not be arch shaped; they may instead have a generally straight axis, as shown for example in Figure 7. The stent of Figure 7 has a  
15       straight central longitudinal axis 30, with a helical centre line 40 which undergoes about half of one turn. The low relative amplitude of the helix of the stent means that it is close to a cylindrical shape and can therefore be used in procedures where conventional  
20       stents would previously have been used. However, this is achieved without departing from a circular cross-sectional shape and without using helical ribs or other projecting formations. It is expected that the vessel into which the stent is inserted will be able to adopt the shape defined by the stent and therefore benefit  
25       from swirl flow. In other embodiments, the helical centre line may undergo more than half of one turn, and indeed more than one or more turns.

      The stent of Figure 7 may be useful as an arterial  
30       stent where there is thrombosis or stenosis of for example coronary arteries.

#### EXAMPLE 1

35       Experiments were carried out using polyvinyl chloride tubing with a circular cross-section. Referring to the parameters shown in Figure 1 the tubing had an external diameter  $D_e$  of 12mm, an internal diameter

$D_I$  of 8mm and a wall thickness  $T$  of 2mm. The tubing was coiled into a helix with a pitch  $P$  of 45mm and a helix angle  $\theta$  of  $8^\circ$ . The amplitude  $A$  was established by resting the tubing between two straight edges and measuring the space between the straight edges. The amplitude was determined by subtracting the external diameter  $D_E$  from the swept width  $W$ :

$$2A = W - D_E$$

So:

$$A = \frac{W - D_E}{2}$$

In this example the swept width  $W$  was 14 mm, so:

$$A = \frac{W - D_E}{2} = \frac{14 - 12}{2} = 1 \text{ mm}$$

As discussed earlier, "relative amplitude"  $A_R$  is defined as:

$$A_R = \frac{A}{D_I}$$

In the case of this Example, therefore:

$$A_R = \frac{A}{D_I} = \frac{1}{8} = 0.125$$

Water was passed along the tube. In order to observe the flow characteristics, two needles 80 and 82 passing radially through the tube wall were used to inject visible dye into the flow. The injection sites were near to the central axis 30, i.e. at the "core" of the flow. One needle 80 injected red ink and the other needle 82 blue ink.

Figure 8 shows the results of three experiments, at Reynolds numbers  $R_E$  of 500, 250 and 100 respectively. It will be seen in all cases that the ink filaments 84 and 86 intertwine, indicating that in the core there is swirl flow, i.e. flow which is generally rotating.

## EXAMPLE 2

The parameters for this Example were the same as in Example 1, except that the needles 80 and 82 were arranged to release the ink filaments 84 and 86 near to the wall of the tubing. Figure 9 shows the results of two experiments with near-wall ink release, with Reynolds numbers  $R_E$  of 500 and 250 respectively. It will be seen that in both cases the ink filaments follow the helical tubing geometry, indicating near-wall swirl. Furthermore, mixing of the ink filaments with the water is promoted.

It will be appreciated that this invention is concerned with values of relative amplitude  $A_R$  less than or equal to 0.5, i.e. small relative amplitudes. In a straight tubing portion both the amplitude  $A$  and the relative amplitude  $A_R$  equal zero, as there is no helix. Therefore, with values of relative amplitude  $A_R$  approaching zero, the ability of the tubing portion to induce swirl will reduce. The lowest workable value of relative amplitude  $A_R$  for any given situation will depend on the speed of flow and the viscosity and density of the fluid (i.e. Reynolds number) and on the pitch (helix angle) and the particular use of the tubing portion.

Claims

1. Artificial or modified natural body fluid flow tubing, or flow tubing used in equipment for conveying  
5 body fluid, comprising a portion wherein the centre line of the tubing portion follows a substantially helical path with a helix angle less than or equal to  $65^\circ$ , and wherein the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing  
10 portion.
2. Tubing as claimed in claim 1, comprising a prosthesis, stent, or vascular access graft.
- 15 3. Tubing as claimed in claim 1 or 2, wherein the pitch of the helix is constant along the tubing portion.
4. Tubing as claimed in claim 1 or 2, wherein the pitch of the helix varies along the tubing portion.  
20
5. Tubing as claimed in any one of claims 1 to 4, wherein the amplitude of the helix is constant along the tubing portion.
- 25 6. Tubing as claimed in any one of claims 1 to 4, wherein the amplitude of the helix varies along the tubing portion.
7. Tubing as claimed in any one of claims 1 to 6,  
30 wherein the tubing portion forms just part of the overall length of the tubing.
8. Tubing as claimed in any one of claims 1 to 6,  
35 wherein the tubing portion extends over substantially the entire length of the tubing.

9. Tubing as claimed in any preceding claim, wherein the centre line of the tubing portion follows a substantially helical path about an axis which is curved.

5

10. Tubing as claimed in any preceding claim, comprising a pharmaceutical coating.

10

11. Artificial or modified natural body fluid flow tubing, or flow tubing used in equipment for conveying body fluid, substantially as hereinbefore described with reference to Figure 2 or Figure 3 or Figure 4 or Figures 5 and 6 or Figure 7 of the accompanying drawings.

---

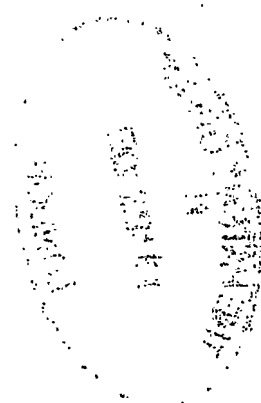
ABSTRACT

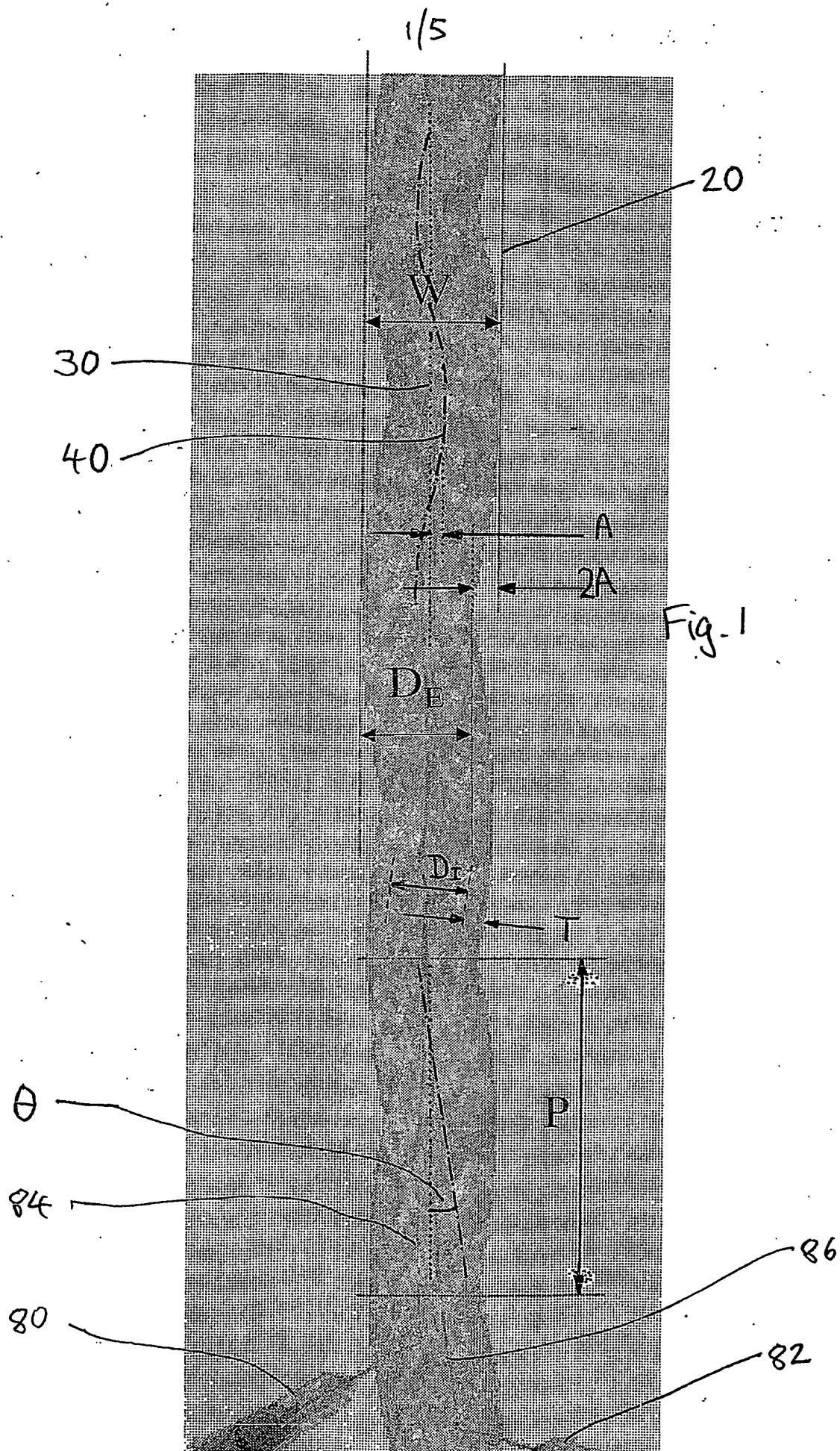
Tubing

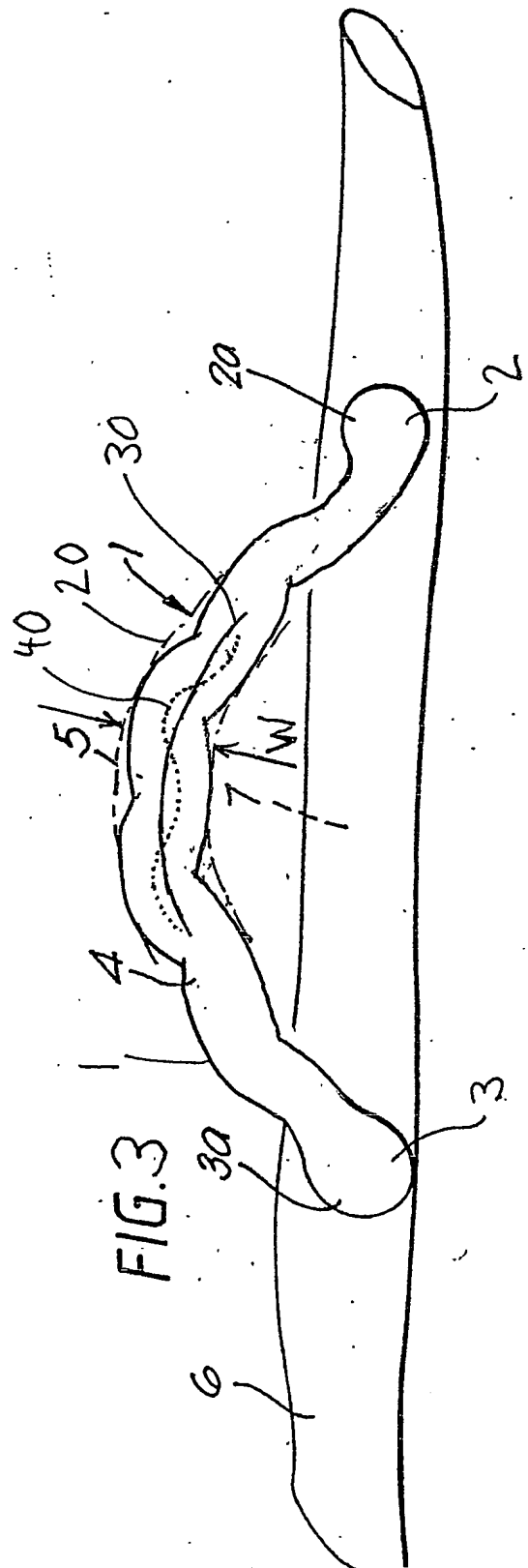
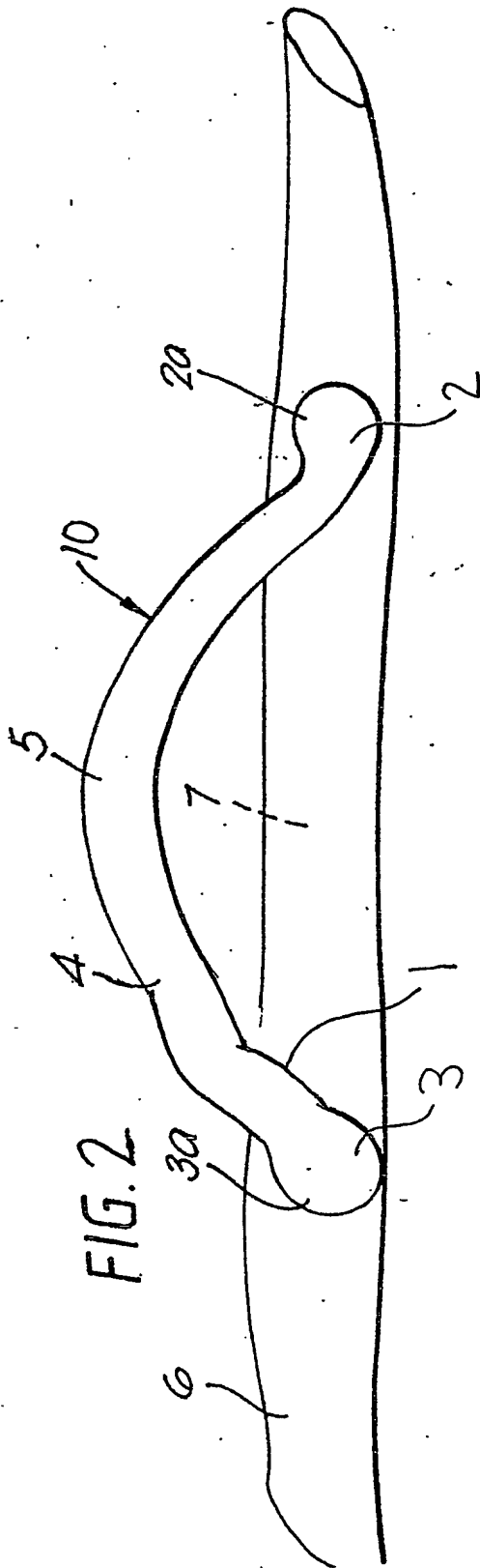
5

10

Artificial or modified natural body fluid tubing,  
or flow tubing used in equipment for conveying body  
fluid, comprising a portion wherein the centre line of  
the tubing portion follows a substantially helical path  
with a helix angle less than or equal to  $65^\circ$ , and  
wherein the amplitude of the helix is less than or equal  
to one half of the internal diameter of the tubing  
portion.









3/5

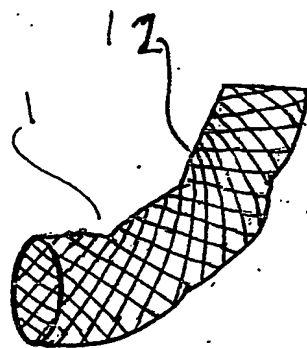


Fig. 4

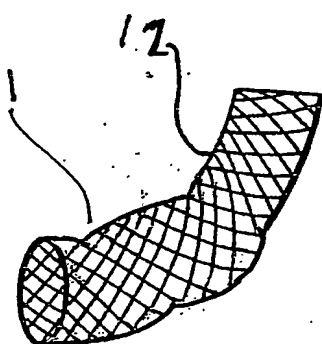


Fig. 5

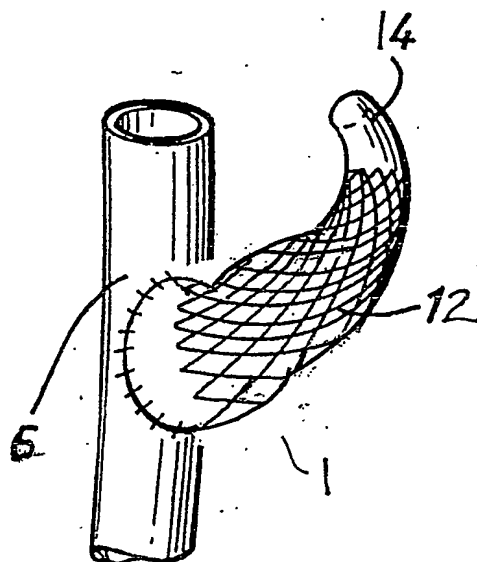


Fig. 6

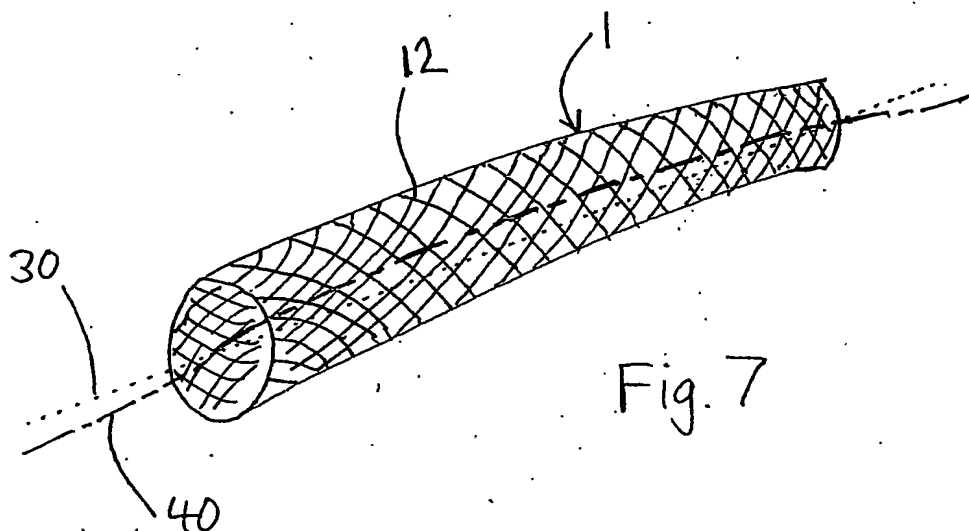


Fig. 7

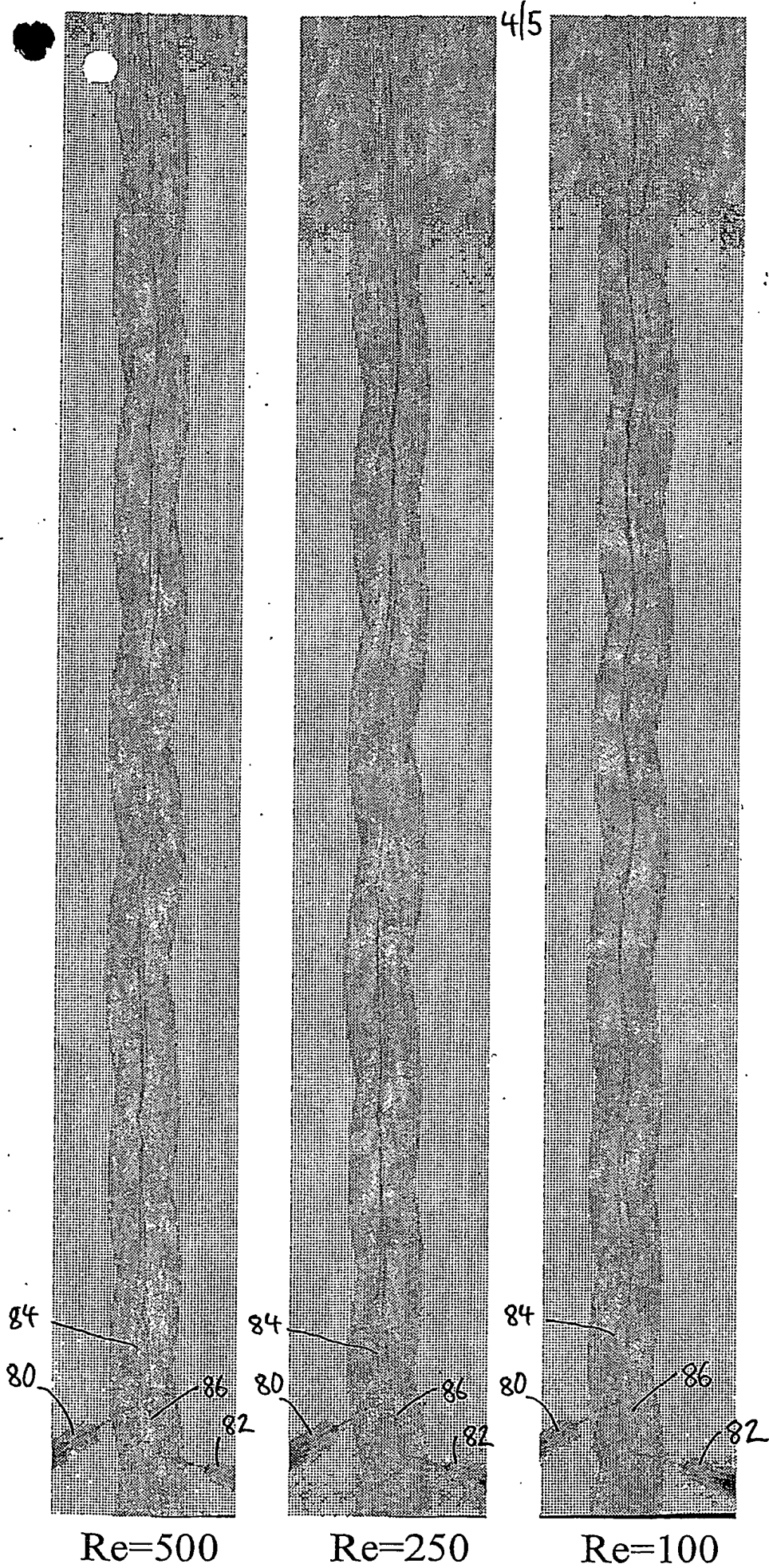


Fig. 8

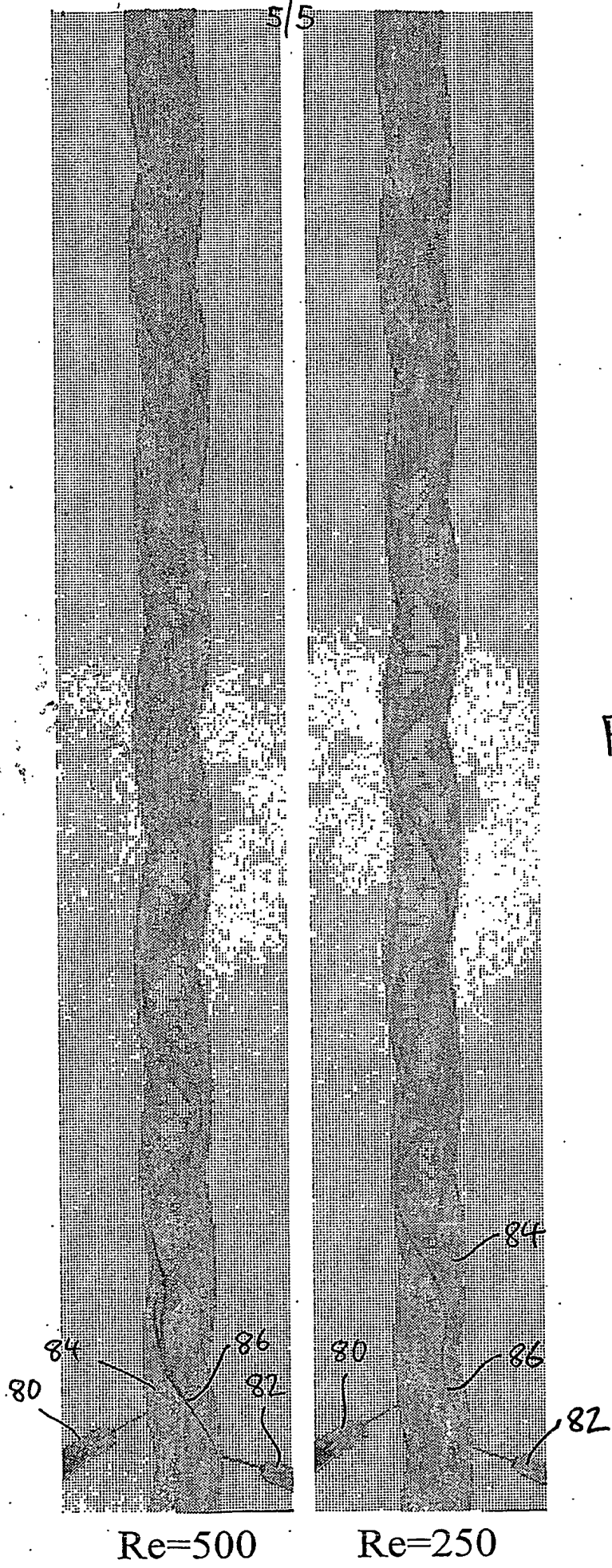


Fig. 9

THE PATENT OFFICE  
22 APR 2004  
Received in Patents  
International Unit

PC/GB04/01155



This Page is inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLORED OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REPERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images  
problems checked, please do not report the  
problems to the IFW Image Problem Mailbox**